



Medline Industries, Inc.

One Medline Place  
Mundelein, Illinois 60060.4486

1.847.949.3109  
1.800.950.0128  
Fax 1.847.949.2643

**Corporate Quality Assurance/Regulatory Affairs**

**SAFETY AND EFFECTIVENESS SUMMARY**

Medline Industries, Inc.

One Medline Place

Mundelein, IL 60060

Phone #: (847) 949-2639

Fax #: (847) 949-2643

Lara N. Simmons

Corporate Regulatory Affairs Manager

K963360

OCT 18 1996

August 21, 1996

Device Name: Protective Restraint, Body Holder  
Proprietary: Medline Body Holder  
Common: Body Holder  
Classification: Protective Restraint

These devices have been legally marketed prior to the date of this submission, and, in fact, prior to 1976. The intended use and claims, technological features, materials and physical and mechanical specifications have not been changed.

**1.0 General Description**

Medline Body Holders are designed for use with either a bed or wheelchair. When used in bed, it may be positioned to secure waist, legs or chest. Belts may be crossed on the front side of the wearer or the back side of the wearer. If limited movement is desired, the belts should be crossed on the front side of the wearer. If the belts are crossed on the back side of the wearer, they will be able to roll from side to side.

For use in a wheelchair, use the front side application ONLY.

**INTENDED USE**

Medline Body Holders may be used either in a bed or wheelchair. They are intended to be used to help prevent patients from falling out of bed. They may be used to restrain the waist, chest, or legs. The Body Holders may be used in one of two ways in bed: First, the belts may be crossed in front of the wearer, providing the greatest amount of restraint and limiting the ability to roll. Second, the belts may be crossed in back of the wearer, allowing the ability to roll. The caregiver must determine the method which best suits the amount of mobility desired and provides the greatest comfort and security for the patient.

For use in a wheelchair, use the front side application ONLY.

**These products are designed for use with a carefully defined medical treatment program which addresses (but is not limited to) restorative nursing, patient release, and pressure sore prevention. Aggressive, agitated or restless patients require increased monitoring and a systematic review and evaluation of both their physical and psychological status.**

**Medline Patient Safety Products are intended to be used for those patients suffering from temporary medical related cognitive deficits, for agitated patients, or to help patients feel safer in a bed or wheelchair.**

**Medline Body Holders are not intended for use with stretchers, on toilets or shower chairs or in the shower or tub, and should always be secured to the movable portion of the bed frame, never to the side rails.**

**Medline Patient Safety Products are not intended for use in a motorized vehicle, as they are not designed to withstand the force of a crash.**

**Medline Patient Safety Products are not intended for home use.**

**These devices are for use in hospitals and/or nursing homes to help maximize patient safety and are not intended to preclude good nursing care and common sense.**

A reasonable search of all information known or otherwise presently available to Medline Industries, Inc. has been conducted. Such a search is defined as examining articles in medical literature, FDA literature, and company documents concerning safety and effectiveness information for safety restraints. Following is a summary of and citation to the safety and effectiveness data found in that search.

Specific safety and effectiveness data outlined in the literature include actual as well as potential complications which may occur and are summarized as follows:

Emotional desolation, agitation, fractures, chafing, burns, nerve damage, circulatory impairment, decubitus ulcers, death, and strangulation attributed to incorrect supervision, handling or application of protective restraint devices by medical or paramedical personnel. These incidences seem to be the result of inappropriate patient selection (physically restraining a patient for whom physical restraint is contraindicated), incorrect restraint selection, errors in correctly applying the device, and/or inadequate monitoring of patients when restrained.

When used correctly and for indicated circumstances, protective restraints provide benefits to many patients, such as precluding patients with temporary medical related cognitive deficits from impairing the resolution of their physical problems by involuntarily discontinuing life-support or other needed medical interventions, temporarily reducing the mobility of agitated patients, or helping patients feel safer in a bed or wheelchair.

Medline Industries, Inc. offers a variety of additional materials to help insure the safe and proper use of its patient safety products, including posters and videos. Medline Industries, Inc. stresses the importance of patient monitoring, and that these products should only be used upon advice of a physician or other trained, licensed healthcare professional.

A total of thirteen articles were reviewed for this 510(k) submission. The articles listed in the citation contained pertinent data for establishing the safety and efficacy of protective restraints.

### CITATION

Physical Restraints: An FDA Update, American Journal of Nursing From FDA Nurses 1992; 74: November 1992, Mary D. Weick, RN, MSN.

Potential Hazards With Protective Restraint Devices; FDA Medical Alert, dated November 14, 1991; MDA91-3

The Misuse of Physical Restraints in the Confused Patient; This paper was presented by Ms. Barbara Fitzgerald, Ward Sister, Geriatric Unit, St. James Hospital Dublin at the INO Nursing Association for the Elderly Day Conference in April, 1986.

Federal Register/Vol. 57, No. 119/Friday, June 19, 1992/ Proposed Rules

Potential Hazards with Physical Restraint Devices; FDA Safety Alert, dated July 15, 1992

Restraint and Seclusion; Journal of Psychosocial Nursing, June 1985, Vol. 23, No. 6, Janice M. Roper, RN, MS, Adam Courtts, MS Janet Sather, RN, and Rosella Taylor, RN.